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REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661			SNOW, BRUCE EDWARD	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/905,683

Filing Date: July 16, 2001

Appellant(s): GROOMS ET AL.

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Jennifer E. Lacroix  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 12/06/07 appealing from the Office action mailed 3/15/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/387,322

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Albee, "Bone Surgery with Machine Tools", April 1936

5,989,289	Coates et al	11-1999
EP 0517030 A2	Siebels	12-1992
5,192,327	Brantigan	3-1993
5,728,159	Stroever et al	3-1998

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 111-118, 120-123, 129-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools) as evidenced by Stroever et al (5,728,159).

Referring to all figures, specifically figure 3, sub-figures 10-12 and 15, Albee teaches:

a first cortical bone portion;  
a second cortical bone portion;  
said first cortical bone portion and said second cortical bone portion having one or more (circular shown in at least figure 3, sub-figure 10) through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body outside the patient and suitable for implantation into said patient.

Note figure 3, subfigures 1, 2a 10, 11, 12, 15 which are interpreted as having through holes.

Albee teaches the pins are grafts which inherently comprise cortical and cancellous bone.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Siebels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it

would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for connecting said first portion to said second portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone.

Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical

bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because “*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*” See column 2, lines 40 et seq. of Coates.

Additionally, “cortical bone with the advantage of incorporation of the spacer material without stress shielding.”

Regarding the amendment to claim 111 including “circular through hole”, circular is defined as “of or relating to a circle”. Elements 14 and 24 are interpreted as being circular. Additionally, the entire opening can be interpreted as the through hole.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have

constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

#### **(10) Response to Argument**

Claims 111-118, 120-123, 129-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools) as evidenced by Stroever et al (5,728,159).

In 1936 Dr. Albee taught, "*grafting bones is much like grafting trees.. bone from your own body.. cut with a circular saw*" can be used to repair broken bones. Dr. Albee further taught that bone surgery is often done with "*pieces of hard and non-living bone, has long been familiar, but Nature often rejects such foreign substances. To repair living bone, living bone is an ideal material.*"

Appellant argues the Albee does not teach assembling the bone implant suitable for implantation into a patient outside of the patient. Albee teaches repairing broken bones using the patients own bone (autograft). It is the Examiner's position that the repaired broken bones or assembled bone portions of a first patient are capable of being used as donor tissue (allograft) and implanted into a second patient which fulfills all functional language. MPEP 2114 teaches:

**APPARATUS CLAIMS MUST BE STRUCTUR-ALLY  
DISTINGUISHABLE FROM THE PRIOR ART**

>While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)

**MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE  
APPARATUS CLAIM FROM THE PRIOR ART**

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

Additionally, in situations of multiple breaks, it is conceivable that bone portions are connected together outside of the body and then placed back, such as skull fractures.

Albee teaches using "round dowels" (or pins) (see Editor's box starting on page 178 and ending on page 179) for reconnecting broken bones; see at least figures 10, 4, 1, 2a showing the use of the dowels. Regarding "circular through holes", a round dowel infers a circular hole. Regarding specifically "through hole", the Examiner notes that the claims only requires "a first cortical bone portion" and a "second cortical bone portion". It is the Examiner's position that the circular holes of Albee extend completely through a **portion** of the first and second portion, for example, the hip of figure 10. It is noted that figure 2a shows the pins completely through the bone portions as does that shown in figure 15.

Regarding at least claim 112 and 130 requiring the first and second cortical bone portion each having a D shape, figures 1 and 2a teach long bones such as the tibia

which inherently have a D shaped cross-section as evidenced by at least figure 7 of Stroever et al (5,728,159).

Regarding at least claim 131 and 136, at least the first and second cortical bone portions shown in figure 10 are "stacked".

Regarding at least claim 116, either side of the break shown in figure 10 are "mirrored" first and second portions.

Regarding at least claim 117, Quick definitions (bevel)

- **noun:** two surfaces meeting at an angle different from 90 degrees

See figure 2a.

Regarding at least claim 121, bone portions of at least figures 2a and 10 are sized and shaped "in the form of a cervical implant".

Regarding at least claim 122, a first and second bone portion can be selected to meet the sizing.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

The Examiner believes the combination of Coates et al in view of Sieblels to be very sound and logical. The reasoning for combining was clearly stated in the grounds of rejection.

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also

teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Coates et al, despite the difficulty of manufacturing, teaches a D-shaped cortical bone implant:

(31) *The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or any of the above prepared in a variety of ways. **Cortical bone is preferred for its compressive strength.** In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape.*

It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have used the teaching of Siebels and have stacked the device of Coates to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon with predictable results; this is an advantage over predetermined sizes.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice.

Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding. Appellant's claimed materials are well known in the art.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

The Examiner believes the combination of Brantigan in view of Coates to very sound, logical and, possible, one of the best reasoning for combining this Examiner has ever made. Coates et al specifically states the problem of Brantigan implant (emphasis added). Coates states, “*5,192,327 to Brantigan teach hollow metal cage structures.*

*Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*” See column 2, lines 40 et seq. of Coates. Coates goes further and solves the

problem of Brantigan teaching, “*various bone grafts.. have been used to promote osteogenesis and to avoid the disadvantages of metal implants. Both allograft and autograft.. (2:49 et seq.)*” “*Cortical bone is preferred for its compressive strength (11:42 et seq.)*”..

Regarding claim 111 including a “circular through hole”, circular is defined as “of or relating to a circle”. Elements 14 and 24 are semi-circles. It is reasonable to state the two semi-circle is “of or relating to a circle”, thus, being circular. Additionally, the entire opening can be interpreted as the through hole.

Claim 126 does not require a circular through hole.

Claim 129 requires “one or more pins of appropriate diameter”. Again, elements 14 and 24 are semi-circles which have a diameter; pin 15 can be described as having an appropriate diameter, the diameter of the elements 14, 24.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would have been inherent/obvious to include the pins.

**(11) Related Proceeding(s) Appendix**

Appellant states “NONE” in the table of contents. See MPEP1205.03 Non-Compliant Appeal Brief and Amended Brief

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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